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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,374

07/30/2003

Jean-Pierre Salaun

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20306

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06/06/2005

EXAMINER

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CHICAGO, IL 60606

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,374

Applicant(s)

Salaun et al

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 4-13 is/are rejected.
- 7) ☐ Claim(s) 4,5 and 7-12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 13/06/2004 5/17/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

S. 001

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### **DETAILED ACTION**

Form N570 received on 4/18/05 have been received and entered.

Claim 14-18 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in the reply filed on 28 Oct 2004. The traverse is not completely persuasive because the search for Group V would not have been coextensive for any one other group and treatment of obesity does not, e.g., require the particulars of inhibiting differentiation of fibroblasts *per se*. Based on applicants' election, on 10/25/04 claims 4, 9-13 are examined with the elected group. Groups I, III, and IV are rejoined with Group II. The restrictions of groups I-IV is withdrawn, and the restriction of between group II and V is maintained.

Claims 4-13 are examined since claims 1-3 have been canceled.

### ***Claim Objections***

Claims 4, 5, 7-10, and 12-13 are objected to because the full spelled out words should precede the abbreviations for "EET", "HETE" in the independent claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by Yani et al., US 5,696,166 ('166). The Yani patent discloses compositions comprising of 12-hydroxy-5,8,14-(Z)-10-(E)-eicosatetraenoic acid (12-HETE) or 11, 12 epoxyeicosatetraenoic acid or derivatives as a pharmaceutical cream, gel, gelatin capsule or patch. Examples include semi viscous gels or other semi –solid compositions column 5 lines 7-28.

As to claim 9, The Yani patent discloses 12 (S) or (R) HETE as a topical ophthalmic formulation (see, e.g., the abstract, and claims 2, 4, and 6 column 6 lines 48+). Column 3 lines 22+ disclose formulations that stimulate mucin ocular production and/or secretion in the conjunctival epithelium and goblet cells when administered to a patient i.e., corrects and/or modulates an organic function. The composition thus, treats dry eye using an effective amount of 12-HETE, or a combination thereof column 5 lines 59+. Consequently, the reference anticipates the claimed invention defined in claims 4 and 9.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yani et al., US 5,696,166 ('166) in view of Wollard et al., Prostaglandins 1989, Vol.38,(4) pages 465-71 and Herbertsson et al., J. of Lipid Research, 1998 Vol 39, pages 237-244 (Please supply complete reference – it is not in the red folder).

Yani teaches the current claim 4 12-hydroxy-5,8,14-(Z)-10-(E)-eicosatetraenoic acid (12-HETE) composition column 4 line 1-55, in an effective amount at column 5 line 47-49 as in claim 5, wherein the composition is administered in the form of gel column 5 lines 27 as disclosed in claims 6 and 11, where the 12-HETE comprises of 12(R) or (S)-HETE column 6 line 50, as in claim 7,8 12 and 13. Yani also teaches of a medical product referred to as pharmaceutical composition that corrects/restores an organic function in humans (example- eye disorder) comprising an effective amount of 12-HETE column 5 lines 7+ also at column 5 lines 50-55 as disclosed in claim 9.

Yani however did not per se teach of inhibition of a fibroblast to an adipocyte, but since 12-HETE is an arachidonic metabolite, one of ordinary skill in the art would have expected differentiation of a fibroblast to occur anyway because arachidonic acids

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metabolites inhibits adipocytes productions which illicit inflammatory response via prostaglandins synthesis.

Wollard teaches of a racemic 12(R,S)- HETE compounds (see abstract) administered topically to humans in effective concentrations (see abstract). Topical application is assumed to be in a form of a patch, gel or cream as topical application is always given as a cream, patch or a gel as taught by Yani.

Herbertsson et al., teach (on page 240, right hand side column underlined), of the detection of 12(S)-HETE to other cells, and in the discussion section on page 242 teach of the expression in preadipocytes which appears to inhibit differentiation to adipocytes as in claim 10.

While the claims differ from Yani et al., in that inhibition of a fibroblast to an adipocyte is not disclosed, it would nevertheless have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer 12-HETE compositions- an arachidonic metabolite, to treat human neutrophils and for cell survival. These compounds are known in the art to bind to human leukemia cell and murine pre-adipocytes. Secondly, the method of inhibition is also and would be expected from the teaching in the Hernertsson *et al.* reference.

Therefore, one of ordinary skill in the art would have expected successful results for administering the 12-HETE compounds to correct and inhibit differentiation of a fibroblast in humans. The cited prior art would have motivated one of skill to properly asses the experimentally results and see the reduction of the fibroblast is clearly taught or at least suggested. Thus, the claims are prima facie obvious over cited prior art.

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No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG  
5/27/05

  
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